# Exhibit A

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**CAMDEN VICINAGE**

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| In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation<br><br>HUMANA INC.<br><br>Plaintiff,<br><br>vs.<br><br>TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ARROW PHARM MALTA LTD., ACTAVIS LLC, ACTAVIS PHARMA, INC., HETERO LABS, LTD., HETERO DRUGS, LTD., HETERO USA INC., CAMBER PHARMACEUTICALS, INC., AUROBINDO PHARMA, LTD., AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA, LLC, TORRENT PRIVATE LIMITED, TORRENT PHARMACEUTICALS, LTD., and TORRENT PHARMA, INC.<br><br>Defendants. | Master Docket No. 19-2875 (RBK/JS)<br><br>**COMPLAINT AND JURY DEMAND**<br><br>Civil Action No. 20-10170 |

**AMENDED COMPLAINT BY HUMANA INC.**

1. Humana Inc. ("Humana" or "Plaintiff") brings this Complaint against Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Arrow Pharm Malta Ltd., Actavis, LLC, Actavis Pharma, Inc., Hetero Labs, Ltd., Hetero Drugs, Ltd., Hetero USA Inc., Camber Pharmaceuticals, Inc., Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., Aurolife Pharma, LLC, Torrent Private Limited, Torrent Pharmaceuticals, Ltd., Torrent Pharma, Inc. (collectively "Defendants"). Through this Complaint Humana seeks damages for injuries caused to it as a result of the Defendants' sales of generic blood pressure medications tainted with

carcinogenic substances that led to those medications' recall by the FDA and removal from the U.S. market.

## I. INTRODUCTION

2. This case arises from adulterated, misbranded, and unapproved valsartan, losartan or irbesartan containing drugs (collectively "sartan containing drugs" or "SCDs") that were designed, manufactured, marketed, distributed, packaged, and sold by Defendants in the United States, and which have been and remain the subject of one of the largest ongoing contaminated drug recalls ever in the United States. These SCDs are non-merchantable and are not of the quality represented by Defendants named herein.

3. Valsartan and its combination therapy with hydrochlorothiazide are the generic versions of the reference listed drugs ("RLDs") Diovan® ("DIOVAN") and Diovan HCT® ("DIOVAN HCT"), respectively. Amlodipine-valsartan and its combination therapy with hydrochlorothiazide are the generic versions of the RLDs of Exforge® ("EXFORGE") and Exforge HCT® ("EXFORGE HCT"), respectively. Losartan potassium is the generic version of the reference listed drug Cozaar® ("COZAAR") and Hyzaar® ("HYZAAR"), respectively. Irbesartan and its combination therapy with hydrochlorothiazide are the generic versions of the reference listed drugs ("RLDs") Avapro® ("AVAPRO") and Avalide® ("AVALIDE"), respectively. These RLDs are indicated for, inter alia, the treatment of high blood pressure, a condition affecting approximately 103 million Americans according to the American Heart Association. Several million U.S. patients pay for (in whole or in part) and consume generic sartan containing drugs each year.

4. Humana, Inc. is a provider of health benefits and related services to over twenty-one million members through various health insurance plans and prescription drug plans, including

Medicare Advantage Plans and Medicare Part D prescription drug plans which insure members against the cost of drugs, including SCDs.

5. Humana brings this action to recover costs that Humana incurred because of Defendants' sales and recalls of adulterated, misbranded, and/or unapproved SCDs illegally manufactured, sold, labeled, marketed, and distributed in the United States as FDA-approved generic versions of DIOVAN, DIOVAN HCT, EXFORGE, EXFORGE HCT, COZAAR, HYZAAR, AVAPRO and AVALIDE. Defendants' generic SCDs were in fact not FDA-approved generic versions of these drugs, and were instead of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) through contamination with IARC- and EPA-listed probable human carcinogens known as N-nitrosodimethylamine ("NDMA"), N-nitrosodiethylamine ("NDEA"), and N-Nitroso-N-methyl-4-aminobutyric acid ("NMBA"). The recall of these tainted drugs from the marketplace caused Humana to incur substantial costs in terms of recalling and replacing those drugs for its members.

6. According to testing by the U.S. Food and Drug Administration ("FDA"), the generic SCDs at issue in this case contained NDMA, NDEA, and/or NMBA contamination levels that were in some cases hundreds of times higher than the FDA's February 28, 2019 updated interim limits for NDMA, NDEA and/or NMBA impurities.

7. On information and belief, the contamination of Defendants' SCDs began in 2011 when Defendants' Active Pharmaceutical Ingredient ("API") manufacturer changed the manufacturing process to include a solvent suspected of producing NDMA, NDEA, NMBA and potentially other contaminants. Defendants had actual or constructive notice of the contamination as early as 2011.

8. Defendants have been illegally manufacturing, selling, labeling, marketing, and distributing the misbranded and/or adulterated SCDs in the United States since as far back as January 2015, when Defendants launched a DIOVAN generic after its valsartan Abbreviated New Drug Application ("ANDA") was approved by the FDA.

9. At all times during the period alleged herein Defendants represented and warranted to Humana that their generic SCDs were therapeutically equivalent to and otherwise the same as their RLDs, were fit for their ordinary uses, and were manufactured and distributed in accordance with applicable laws and regulations.

10. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at several of the overseas manufacturing plants where Defendants' generic SCDs were manufactured for import to the United States, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed adulterated and/or misbranded SCDs for purchase and reimbursement in the United States by Humana.

11. Humana purchased or made reimbursements for generic SCDs that were illegally and willfully introduced into the market by Defendants, causing Humana to sustain economic damages.

12. Defendants' generic SCDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs since at least 2015. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state and federal law as set forth herein.

## II. PARTIES

### A. Plaintiff

13. Plaintiff Humana Inc. is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky. The following subsidiaries of Humana Inc. provide

medical coverage in various states and regions throughout all 50 States and Puerto Rico: Arcadian Health Plan, Inc., CarePlus Health Plans, Inc., Cariten Health Plan, Inc., Cariten Insurance Company, CHA HMO, Inc., Emphesys Insurance Company, Humana Behavioral Health, Inc., Humana Benefit Plan of Illinois, Inc., HumanaDental, Inc., Humana Employers Health Plan of Georgia, Inc., Humana Health Benefit Plan of Louisiana, Inc., Humana Health Company of New York, Inc., Humana Health Insurance Company of Florida, Inc., Humana Health Plan of California, Inc., Humana Health Plan of Ohio, Inc., Humana Health Plan of Texas, Inc., Humana Health Plan, Inc., Humana Health Plans of Puerto Rico, Inc., Humana Insurance Company, Humana Insurance Company of Kentucky, Humana Insurance Company of New York, Humana Insurance of Puerto Rico, Inc., Humana Medical Plan of Pennsylvania, Inc., Humana Medical Plan of Utah, Inc., Humana Medical Plan, Inc., Humana Medical Plan of Michigan, Inc., Humana Regional Health Plan, Inc., Health Value Management, Inc. d/b/a ChoiceCare Network, and Humana Wisconsin Health Organization Insurance Corporation (collectively, the "Operating Subsidiaries"). The Operating Subsidiaries have assigned the claims asserted here to Humana Inc.

## B. Defendants

### 1. Teva Defendants

14. Defendant Teva Pharmaceutical Industries Ltd. ("Teva") is a foreign company incorporated and headquartered in Petah Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic SCDs in the United States.

15. Defendant Teva Pharmaceutical Industries Ltd. ("Teva") is a foreign company incorporated and headquartered in Petah Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and

possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic SCDs in the United States.

16. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is a wholly owned subsidiary of Teva. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic SCDs in the United States.

17. Arrow Pharm Malta Ltd. ("Arrow") is a foreign corporation headquartered at HF62 HalFar Industrial Estate, HalFar, BBG 300, Malta. Teva owns the entirety of Arrow, which on its own and/or through its parent company and subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Arrow has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded SCDs in the United States.

18. Actavis Pharma, Inc. ("Actavis Pharma") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly owned subsidiary. At all times material to this case, Actavis Pharma has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded SCDs in the United States.

19. Actavis, LLC ("Actavis") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly owned subsidiary. At all times material to this case, Actavis has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded SCDs in the United States.

20. Teva,Teva USA, Arrow, and Actavis Pharma are collectively referred to as the Teva Defendants in this Complaint.

**2. Hetero Defendants**

20. Defendant Hetero Labs, Ltd. ("Hetero Labs") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Telangana, India. Hetero Labs on its own and/or through its subsidiaries regularly conducts business in New Jersey and throughout the United States and its territories and possessions. At all times material to this action, Hetero Labs has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved generic SCDs throughout the United States.

21. Defendant Hetero Drugs, Limited ("Hetero") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Telangana, India. Hetero claims that it "has a strong established global presence with 36 manufacturing facilities and a robust network of business partners and marketing offices strategically located across the world." Hetero on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. Hetero Labs is the wholly owned subsidiary of Hetero. At all times material to this action, Hetero has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved generic SCDs throughout the United States.

22. Defendant Hetero USA Inc. ("Hetero USA") is "the US representation of HETERO, a privately owned; researched based global pharmaceutical company." Hetero USA is a Delaware corporation with its principal place of business located at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero USA is the wholly owned subsidiary of Hetero. At all times

material to this action, Hetero USA has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved generic SCDs throughout the United States.

23. Defendant Camber Pharmaceuticals, Inc. ("Camber") is a Delaware corporation, with its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. Camber is the wholly owned subsidiary of Hetero Drugs. At all times material to this action, Camber has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved SCDs throughout the United States.

24. Collectively, Hetero Labs, Hetero, Hetero USA, and Camber will be referred to as the Hetero Defendants in this Complaint.

25. Valsartan-containing API manufactured by Hetero was distributed to Hetero's U.S. subsidiaries or affiliates including Hetero USA and Camber. In turn, Camber supplied Hetero-manufactured valsartan API to at least three repackagers, including AvKARE, Inc., RemedyRepack, Inc., and Preferred Pharmaceuticals. The Hetero Defendants also manufactured losartan-containing API for the following other manufacturers: Torrent Defendants, Teva Defendants, Vivimed Life Sciences, Heritage Pharmaceuticals, and Macleods Pharmaceuticals.

### 3. Aurobindo Defendants

26. Defendant Aurobindo Pharma, Ltd. ("Aurobindo") is a foreign corporation with its principal place of business at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad-500038 Telangana, India, and a United States headquarters at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Aurobindo has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded SCDs in the United States.

27. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a Delaware corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. It is a wholly owned subsidiary of Aurobindo. At all times material to this case, Aurobindo USA has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved SCDs in the United States.

28. Defendant Aurolife Pharma, LLC ("Aurolife") is a Delaware limited liability company with its principal place of business at 2400 US-130, North, Dayton, New Jersey 08810. It is a wholly owned subsidiary of Aurobindo USA. At all times material to this case, Aurolife has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded and/or unapproved SCDs in the United States.

29. Aurobindo, Aurobindo USA, and Aurolife are collectively referred to as the Aurobindo Defendants in this Complaint.

30. Aurobindo's valsartan-containing API was supplied in large part to itself due to its vertically integrated supply chain. Aurobindo adds value through superior customer service in the distribution of a broad line of generic pharmaceuticals, leveraging vertical integration and efficient controlled processes.

31. NDEA contaminated irbesartan-containing API manufactured by Aurobindo was supplied to at least one other company in the United States, ScieGen.

#### 4. Torrent Defendants

32. Defendant Torrent Private Limited ("Torrent") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Torrent on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case,

Torrent has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded SCDs in the United States.

33. Defendant Torrent Pharmaceuticals, Ltd. ("Torrent Pharmaceuticals") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Over 70% of Torrent Pharmaceuticals is owned by Torrent. Torrent Pharmaceuticals on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Torrent Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded SCDs in the United States.

34. Defendant Torrent Pharma, Inc. ("Torrent Pharma") is a Delaware corporation with its principal place of business at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. It is a wholly owned subsidiary of Torrent Pharmaceuticals. At all times material to this case, Torrent Pharma has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded and/or unapproved SCDs in the United States.

35. Torrent, Torrent Pharmaceuticals, and Torrent Pharma are referred to collectively as the Torrent Defendants in this Complaint.

### C. Zhejiang Huahai Pharmaceutical – API Supplier to Multiple Defendants

36. Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. The company also has United States headquarters located at 2009 and 2002 Eastpark Blvd., Cranbury, NJ 08512. Much of the VCDs manufactured by the ZHP contained NDMA levels hundreds of times higher than acceptable limits for human consumption, according to laboratory results published by the FDA. Some of its SCDs also contained NDEA. ZHP manufactured valsartan-containing API for the Teva

Defendants and Torrent Defendants to use in manufacturing their SCDs. NDEA-contaminated losartan-containing API manufactured by ZHP was supplied to at least one other company in the United States, Sandoz.

## III. JURISDICTION AND VENUE

37. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331, in that this is a civil action arising under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq.*

38. This Court may exercise supplemental jurisdiction under 28 U.S.C. § 1367 over the state-law claims asserted in this action, because they arise out of the same case or controversy.

39. This Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1407, and because Defendants have sufficient minimum contacts in New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

40. This case is being directly filed in the Multi-District Litigation docket number MDL No. 2875 in the United States District Court for the District of New Jersey in accordance with Case Management Order No. 3 (Doc. 76) in *In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Master Docket No. 19-2875 (RBK/JS).

41. Upon remand, venue is proper in the United States District Court for the District of Delaware because Defendants reside in that District, 28 U.S.C. § 1391(b)(1); "a substantial part of the events or omissions giving rise to the claim occurred" in that District, 28 U.S.C. § 1391(b)(2); and Defendants are subject to the personal jurisdiction of the Court in that district, 28 U.S.C. § 1391(b)(3).

## III. FACTUAL ALLEGATIONS

### A. Prescription Drug Reimbursement

42. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

43. Pharmaceutical manufacturers produce drugs which they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

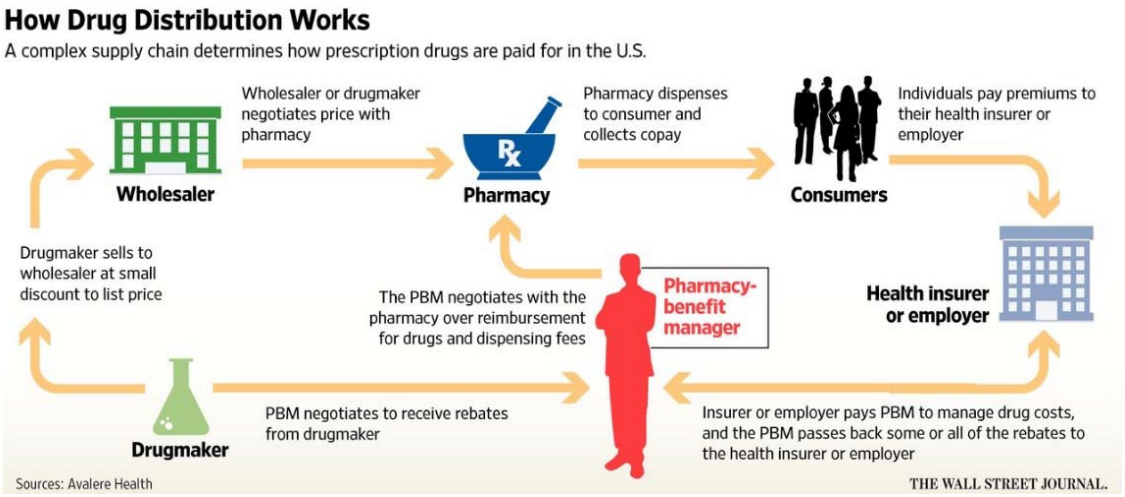
44. Third Party Payors ("TPPs") contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing generic drugs, such as SCDs, on the TPPs' formularies.

45. In conducting formulary management, TPPs and their PBMs reasonably expect that generic prescription drugs reimbursable on their formularies are bioequivalent or otherwise the same as their RLD counterparts. As is the case with all generic drugs, TPPs seek to include the lowest cost generic drugs possible in their formularies. This is only made possible because of the manufacturers' and distributors' representations that these generic drugs, such as the Defendants' SCDs, comply with their respective ANDAs, which state that the generic drugs are bioequivalent to their respective branded drug. Thus, the TPPs permitted the SCDs to be included on their formularies based on the Defendants' misrepresentations that their SCDs were bioequivalent to brand-named DIOVAN/HCT, EXFORGE/HCT, COZAAR, HYZAAR, AVAPRO and/or

AVALIDE, complied with all current Good Manufacturing Practices ("cGMPs"), and were safe for consumption.

46. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co-payment, and the higher likelihood that the drug will be purchased by plan beneficiaries in lieu of a more expensive alternative, and vice versa. As such, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

47. The following chart, published by the Wall Street Journal, broadly illustrates the pharmaceutical supply chain:




48. When a patient presents his/her prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBMs for reimbursement. PBMs then cumulate those individual reimbursements and present them to TPPs for payment.

**B. Generic Drugs Must Be Chemically the Same as Branded Drug Equivalents**

49. According to the FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as its brand-name version. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."

50. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA, which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient(s) in the generic medicine is/are the same as in the brand-name drug/innovator drug.

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.

51. The drugs paid for by Humana and ingested by Humana's insureds were approved by the FDA, based upon Defendants' representations that they met the above criteria.

52. ANDA applications do not require drug manufacturers to repeat animal studies or

clinical research on ingredients or dosage forms already approved for safety and effectiveness.

53. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.

### C. Adulterated or Misbranded Drugs

54. The manufacture of any adulterated or misbranded drug is prohibited under federal law. 21 U.S.C. § 331(g).

55. The introduction into commerce of any adulterated or misbranded drug is similarly prohibited. 21 U.S.C. § 331(a).

56. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful. 21 U.S.C. § 331(c).

57. Among the ways a drug may be adulterated and/or misbranded are:

a. "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health," 21 U.S.C. § 351(a)(2)(A);

b. "if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess," 21 U.S.C. § 351(a)(2)(B);

c. "[i]f it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium," 21 U.S.C. § 351(b); and

d. "[i]f . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor." 21 U.S.C. § 351(d).

58. A drug is misbranded:

a. "[i]f its labeling is false or misleading in any particular," 21 U.S.C. § 352(a)(1);

b. "[i]f any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use," 21 U.S.C. § 352(c);

c. if the labeling does not contain, among other things, "the proportion of each active ingredient," 21 U.S.C. § 352(e)(1)(A)(ii);

d. if its label does not bear "(1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users," 21 U.S.C. § 352(f);

e. "[i]f it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein," 21 U.S.C. § 352(g);

f. "if it is an imitation of another drug," 21 U.S.C. § 352(i)(2);

g. "if it is offered for sale under the name of another drug," 21 U.S.C. § 352(i)(3);

h. "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," 21 U.S.C. § 352(j);

i. if the drug is advertised incorrectly in any manner, 21 U.S.C. § 352(n); or

j. if the drug's "packaging or labeling is in violation of an applicable regulation." 21 U.S.C. § 352(p).

59. As articulated in this Complaint, Defendants' unapproved drug was adulterated and/or misbranded in violation of all of the above-cited reasons.

### D. The Drugs Purchased or Reimbursed by Humana Were Not Valsartan, Losartan or Irbesartan, But New, Unapproved SCDs Not of the Same Quality

60. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.

61. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

62. NDMA NDEA, and NMBA have the ability to cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, NDMA, NDEA, and NMBA are, by definition, active ingredients in a drug.

63. The FDA further requires that whenever a new active ingredient is added to a drug,

the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product. *See* 21 C.F.R. § 310.3(h).

64. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject SCDs) cannot be required to have the same label as the brand-name drug, as the two products are no longer the same.

65. At the very least and alternatively, drugs with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.

66. Because the SCDs purchased or reimbursed by Humana were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

67. The inclusion of additional active ingredients (NDMA, NDEA, and NMBA), and potentially other deviations from Defendants' ANDA approvals rendered Defendants' SCDs of a lesser quality than FDA-approved generic valsartan, losartan, and irbesartan.

68. Humana's reference to federal law in this Complaint is not in any attempt to enforce it, but to demonstrate that Humana's state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

### E. Defendants Made False Statements in the Labeling of Their SCDs

69. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended," 21 C.F.R. § 201.5, and conform to requirements governing the appearance of the label. 21 C.F.R. § 201.15.

70. Labeling encompasses all written, printed or graphic material accompanying the drug or device, and therefore broadly encompasses nearly every form of promotional activity, including not only package inserts but also advertising.

71. Most, if not all, labeling is advertising. The term "labeling" is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

72. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded. 21 C.F.R. § 201.6; 201.10.

73. Because NDMA, NDEA, and/or NMBA were not disclosed by Defendants as ingredients in the SCDs purchased or reimbursed by Humana, the subject drugs were misbranded.

74. In addition, by referring to their drugs as "valsartan" or "valsartan HCT" or "amlodipine-valsartan" or "amlodipine-valsartan HCT" or "losartan potassium" or "losartan potassium-hydrochlorothiazide" or "irbesartan" or "irbesartan-hydrochlorothiazide" Defendants were making false statements regarding their SCDs.

75. It is unlawful to introduce a misbranded drug into interstate commerce. 21 U.S.C. § 331(a). Thus, the SCDs purchased or reimbursed by Humana were unlawfully distributed and sold.

### F. The Generic Drug Supply Chain in the United States

76. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

77. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, API manufacturers). Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

78. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

79. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions and their insurers.

**G. Background on Current Good Manufacturing Practices**

80. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. See 21 U.S.C. § 351(a)(2)(B).

81. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

82. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding organization and personnel (Part 211, Subpart B); buildings and facilities (Part 211, Subpart C); equipment (Part 211, Subpart D); control of components and drug product containers and closures (Part 211, Subpart E); production and process controls (Part 211, Subpart F); packaging and label controls (Part 211, Subpart G); holding and distribution (Part 211, Subpart H); laboratory controls (Part 211, Subpart I); records and reports (Part 211, Subpart J); and returned and salvaged drug products (Part 211, Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs

intended to be distributed in the United States.

83. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. See 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

84. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351. Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

85. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

86. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

87. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials,

labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160(b).

88. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and "[a] statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

## H. The Generic Drug Approval Framework

89. The Drug Price Competition and Patent Term Restoration Act of 1984—more commonly referred to as the Hatch-Waxman Act—is codified at 21 U.S.C. § 355(j).

90. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

91. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

92. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or RLD. Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1; 21 C.F.R. § 314.3(b).

### *1. ANDA Applications Must Demonstrate Bioequivalence*

93. The bioequivalence basis for ANDA approval is premised on the generally

accepted proposition that equivalence of pharmacokinetic profiles of two drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

94. As part of its showing of bioequivalence pursuant to 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

- a full description of the drug's substance, including its physical and chemical characteristics and stability; and
- the specifications necessary to ensure the identity strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

95. Generic drug manufacturers have an ongoing federal duty of sameness in their products. The generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, 21 U.S.C. § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* § 355(j)(2) (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. 21 U.S.C. § 355(j)(2)(A)(vi); *see also id.* § 355(b)(1)(C).

96. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

### *2. ANDA Applications Must Provide Information About the Manufacturing Plants and Processes*

97. The ANDA application must also include information about the manufacturing

facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

98. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

99. Furthermore, the ANDA application must contain information pertaining to the manufacturing facility's validation process which ensures that the manufacturing process produces a dosage that meets product specifications.

### *3. ANDA Applications Must Comply with cGMPs*

100. Additionally, ANDA applications must include certain representations pertaining to compliance with cGMPS.

101. The ANDA application is required to contain cGMP certifications for both the ANDA applicant itself, and also the drug product manufacturer (if they are different entities).

### *4. ANDA Approval Is Contingent upon Continuing Compliance with ANDA Representations of Sameness*

102. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name (e.g., valsartan or valsartan HCT), generic manufacturers impliedly warrant that the generic drug is therapeutically equivalent to the brand-name drug.

103. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

104. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

105. According to the FDA, there are at least sixteen ANDAs approved for generic DIOVAN, nine for generic DIOVAN HCT, nine for generic EXFORGE, five for generic EXFORGE HCT, fifteen for generic COZAAR, eleven for generic HYZAAR, fourteen for generic AVAPRO, and ten for generic AVALIDE.

## I. Approval of ANDAs Related to Valsartan

### *1. DIOVAN and EXFORGE Background*

106. Valsartan is a potent, orally active nonpeptide tetrazole derivative which causes a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction. Millions of American consumers use SCDs for the treatment of these serious conditions, both as a stand-alone drug, and in combination with other therapies (such as amlodipine and hydrochlorothiazide.)

107. Valsartan and its combination therapy with hydrochlorothiazide are the generic versions of the DIOVAN and DIOVAN HCT, which were marketed in tablet form by Novartis AG ("Novartis") beginning in July 2001 (in tablet form) and March 1998, respectively, upon approval by the FDA.

108. Valsartan's combination therapy with amlodipine, as well as the combination therapy of valsartan, amlodipine and hydrochlorothiazide, are the generic versions of Novartis's branded products EXFORGE and EXFORGE HCT. Novartis received the FDA's approval for

EXFORGE in June 2007 and for EXFORGE HCT in April 2009.

109. These Valsartan-based branded drugs proved to be blockbuster products for Novartis. Globally, DIOVAN and DIOVAN HCT generated $5.6 billion in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States. The same year, EXFORGE and EXFORGE HCT had $325,000,000 in U.S. sales and $884,000,000 globally.

110. DIOVAN's, DIOVAN HCT's, EXFORGE's, and EXFORGE HCT's FDA-approved labels specify the active and inactive ingredients. None of the contaminants at issue here (including NDMA, NDEA, or other nitrosamines) are FDA-approved ingredients of DIOVAN, DIOVAN HCT, EXFORGE, or EXFORGE HCT. Nor are any of these contaminants FDA-approved ingredients of any generic valsartan-containing product approved pursuant to an ANDA.

111. Novartis's DIOVAN and EXFORGE patents expired in September 2012. Mylan launched a DIOVAN HCT generic in or about September 2012 when its valsartan HCT ANDA was approved by the FDA. Generic versions of the other drugs followed in the intervening years.

***2. ANDA Applications for Generic Valsartan***

112. Almost a full decade before the DIOVAN patents were set to expire, generic drug manufacturers started filing ANDA applications for their own generic versions of the Valsartan drug.

113. Hatch-Waxman rewards the first generic company to file a substantially complete ANDA containing a Paragraph IV certification with a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is triggered upon either a first commercial marketing of the drug (including of the RLD) by the 180-day exclusivity holder or the date on which a court has entered a judgment finding that the patent subject to the Paragraph IV certification is invalid, unenforceable, or not infringed.

114. On December 24, 2004, Ranbaxy Labs ("Ranbaxy") filed the first ANDA application for Valsartan (the generic equivalent of the DIOVAN product).

115. On January 7, 2005, Teva filed the second ANDA application for Valsartan (the generic equivalent of the DIOVAN product), for which it received tentative approval on January 7, 2005.

116. On September 15, 2008, Mylan N.V. ("Mylan") filed an ANDA application for Valsartan (the generic equivalent of the DIOVAN product).

117. In the intervening years after these three initial ANDA applications, other manufacturers, including ZHP, filed ANDA applications for either Valsartan (the generic equivalent of the DIOVAN product), Valsartan hydrochlorothiazide (the generic equivalent of the DIOVAN HCT product), Valsartan Amlodipine (the generic equivalent of the EXFORGE product), and Valsartan Amlodipine Hydrochlorothiazide (the generic equivalent of the EXFORGE HCT product).

118. Despite the number of ANDAs that had been filed as early as 2004, when DIOVAN's patent expired in 2012, no generic entered the market.

119. As the first to have filed their ANDA application in December of 2004, Ranbaxy was entitled to exclusivity, and as such, no other ANDAs would be approved until Ranbaxy received final approval.

120. Mylan and Teva were among those who had tentative approval and were ready to launch their generic DIOVAN Product upon expiration of the DIOVAN patent in 2012.

121. Indeed, Mylan launched its generic DIOVAN HCT product, for which it had filed an ANDA and received approval, on September 21, 2012, the same day the DIOVAN patent was set to expire.

122. After delaying its approval due to gross manufacturing defects plaguing Ranbaxy's Indian API manufacturing facilities, the FDA finally approved Ranbaxy's generic Valsartan in June of 2014.

123. Six months later, after Ranbaxy's period of exclusivity expired, Mylan's generic DIOVAN product launched on January 5, 2015, and Teva's generic SCDs launched January 6, 2015. The entry of the rest of the generic equivalents of these drugs followed thereafter.

124. Par Pharmaceuticals received approval of the first generic EXFORGE in September 2014, and Teva received approval of the first generic EXFORGE HCT in December 2014. The entry of the rest of the generic equivalents of these drugs followed thereafter.

***2. ANDA Applications for Other SCDs***

125. Teva received approval to be the first-to-market generic COZAAR and HYZAAR in April 2010. The entry of the rest of the generic equivalents of these drugs followed thereafter.

126. Teva received approval to be the first-to-market generic AVAPRO and AVALIDE in April 2012. The entry of the rest of the generic equivalents of these drugs followed thereafter.

**J. Starting as Early as 2007, Defendants Were Actively Violating cGMPs in Their Foreign Manufacturing Facilities**

127. For some time, Defendants have known that generic drugs manufactured overseas, particularly in China and India, were found or suspected to be less safe and effective than their branded equivalents or domestically made generics due to their grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

128. The foreign manufacturing operations that Defendants utilize were no exception to this.

129. ZHP has API manufacturing facilities located in Linhai City, Zhejiang Province, China. According to ZHP's website, ZHP was one of the first Chinese companies approved to sell

generic drugs in the United States, and it remains one of China's largest exporters of pharmaceuticals to the United States and the European Union.

130. ZHP serves as a contract API manufacturer of numerous SCDs, including Defendants, and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

131. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

132. On or about March 27–30, 2007, the FDA inspected ZHP's Xunqiao Linhai City facilities. That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

133. The FDA inspected ZHP's same Xunqiao facility again on November 14–18, 2016. The inspection revealed four violations of cGMPs. First, "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile are not followed." Second, ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." Third, "[p]rocessing areas are deficient regarding the system for cleaning and disinfecting the equipment." Last, "data is not recorded contemporaneously."

134. On May 15–19, 2017, the FDA inspected ZHP's facility at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai City, Zhejiang Province, China. ZHP manufactures all of its valsartan API at this Chuannan facility. That inspection resulted in the FDA's finding that ZHP

repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter and investigation up to that point. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated." These findings were not made fully available to the public. However, this information was shared or available to ZHP's finished-dose manufacturers.

135. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution from the environment" surrounding the facility. These manipulations of sampling were components of a pattern and practice of systematic data manipulation designed to fail to detect and/or intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA and NDEA.

136. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and there were black metallic particles in API batches.

137. The FDA inspector "noted reoccurring complaints pertained to particulate matter in API . . . and for discrepancies in testing between [ZHP] and their consignees. To address the firm's handling of complaints describing testing disparities, [the inspector] had the firm generate a list of such complaints, as well as associated pie charts From 2015 until May 2017, 13 complaints related to discrepancies between [ZHP]'s test results and their consignees results. Of these complaints 85% had what the firm termed 'Customer has no subsequent feedback or treatment.'

Specifically, this 85% was further broken down into 3 categories: the batch subject to the complaint was sent to other consignees who did not report a complaint, there is a test method discrepancy and feedback was provided to the consignee without a response and the consignee failed to respond but continued to purchase API from [ZHP]."

138. On November 29, 2018, the FDA issued Warning Letter 320-19-04 to ZHP based on its July 23 to August 3, 2018 inspection of its Chuannan facility. The letter summarized "significant deviations from [cGMPs] for [APIs]." The FDA consequently informed ZHP that its "API are adulterated and/or misbranded within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

139. The FDA explained that ZHP repeatedly failed "to ensure that quality-related complaints are investigated and resolved," including complaints related to peaks of NDMA in its products as early as 2012.

140. ZHP also failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." More specifically, ZHP "approved a [V]alsartan API process change . . . that included the use of the solvent [redacted]. [ZHP's] intention was to improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities[, such as NDMA,] when [it] implemented the new process. Specifically, [it] did not consider the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted]. According to [ZHP's] ongoing investigation, [redacted] is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process."

141. The FDA added that ZHP "also failed to evaluate the need for additional analytical

methods to ensure that unanticipated impurities were appropriately detected and controlled in [its] [V]alsartan API before [it] approved the process change. [ZHP is] responsible for developing and using suitable methods to detect impurities when developing, and making changes to, [its] manufacturing processes."

142. ZHP claimed that it had followed "common industry practice." Importantly, the FDA reminded ZHP that "common industry practice may not always be consistent with CGMP requirements and that [it is] responsible for the quality of drugs [it] produce[s]." The FDA "strongly" recommended that ZHP hire a cGMP consultant and referred ZHP to four guides on cGMPs.

143. On September 28, 2018, the FDA stopped allowing ZHP to deliver drugs made at its Chuannan facility into the United States. The Warning Letter stated that "[f]ailure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at [ZHP's Chuannan facility] into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B)."

144. After the recalls of ZHP's SCDs, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at its Linhai City facilities contained NDMA levels hundreds of times in excess of the FDA's interim limits of 96 ng/day or 0.3 ppm. Specifically, SCDs manufactured at ZHP for ZHP's subsidiary Prinston Pharmaceutical contained NDMA levels of between 15,180 and 16,300 ng, while Valsartan HCT manufactured at ZHP contained NDMA levels of between 13,180 and 20,190 ng. ZHP valsartan API manufactured for Teva and Torrent Pharmaceuticals contained similarly high levels of NDMA.

145. In addition, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at ZHP's Linhai City facilities for Torrent Pharmaceuticals contained NDEA levels upwards of fifty times in excess of the FDA's interim limits of 26.5 ng/day or 0.083 ppm. Specifically, FDA testing reveals up to 1,310 ng of NDEA in Torrent Pharmaceuticals' SCDs. ZHP valsartan API manufactured for Teva contained similarly high levels of NDEA (up to 770 ng).

### *1. Aurobindo's cGMP violations*

146. On July 20, 2019 the FDA issued a warning letter to Aurobindo Pharma Limited relating to its February 4-9, 2019 inspections of its manufacturing facility at Pydibhimavaram, Ranasthalam (Mandal), Srikakulam District, AP, India. The letter cataloged numerous violations of cGMP with respect to Aurobindo's manufacturing at that facility. Specifically, the FDA found that Aurobindo's investigation into impurities in API that it had manufactured was deficient. It also concluded that Aurobindo had failed to "ensure that equipment surfaces in contact with API do not alter the quality of the API beyond the official or other established specifications."

147. The warning letter also noted that Aurobindo's problems were not limited to the facility at issue. Rather the FDA had noted "similar CGMP" violations "at other facilities in your company's network. Aurobindo Unit I and Aurobindo Unit IX were also inspected and cited for CGMP deficiencies" related to manufacturing of API. The FDA concluded that, "[t]hese facilities are also considered to be in an unacceptable state of compliance with regards to CGMP. These repeated failures at multiple sites demonstrate that management oversight and control over the manufacture of drugs are inadequate."

### *2. Torrent's cGMP violations*

148. On October 8, 2019 the FDA issued a warning letter to Torrent Pharmaceuticals Limited relating to its April 8-16, 2019 inspections of its manufacturing facility at Ahmedabad-

Mehsana Highway, Taluka-Kadi, Indrad, Gujarat, India. The letter cataloged numerous violations of cGMP with respect to Torrent's manufacturing of Losartan Potassium tablets. Specifically, the FDA found that Torrent's quality control procedures rejected multiple batches of API but despite these rejections, Torrent "developed a new interim protocol to justify commercial use of the alternate API and circumvented your original protocol, even though you had data demonstrating your process was not capable of producing quality material using the new alternate API. Numerous Losartan Potassium Tablets USP 50 mg and USP 100 mg commercial batches were manufactured with this new alternate API and released to the U.S. market despite the PV failures. In addition, multiple batches of Losartan Potassium were recalled for unacceptable amounts of nitrosamine impurities."

149. Torrent's written response to the FDA admitted that it did not follow its own "written and approved validation protocols." In addition, the FDA also determined that Torrent's investigations into their testing results of rejected API were inadequate, and that despite those inadequate investigations Torrent "disregarded initial failing out-of-specification results and released batches based on retested results." Torrent had a "high percentage rate (60–70%) for invalidated initial OOS test results between January 2017 and March 2019."

150. The FDA noted that Torrent's problems were not limited to the April 2019 inspection, but rather they were the continuation of a trend. The FDA observed similar problems in an April 17–28, 2017 inspection of Torrent's Indrad facility and it cited "a similar CGMP observation for inadequate investigations" at the Torrent Dahej facility in Gujarat during a March 11–19, 2019 inspection. The FDA concluded that "[r]epeated failures at multiple sites demonstrate that executive management oversight and control over the manufacture of drugs is inadequate."

## K. The Contamination of the SCDs

### *1. The Nitrosamine Contaminant NDMA*

151. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid.

152. According to the U.S. Environmental Protection Agency ("EPA"), "NDMA is a semivolatile chemical that forms in both industrial and natural processes."

153. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

154. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.

155. The U.S. Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen. This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.

156. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.

157. Exposure to high levels of NDMA has been linked to liver damage in humans.

158. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding.

159. Other studies showed an increase in other types of cancers, including but not limited to stomach, colorectal, intestinal, kidney, liver, and other digestive tract cancers.

160. On July 27, 2018, the FDA put out a press release, explaining the reason for its concern regarding the presence of NDMA found in SCDs. In that statement, the FDA provided, in relevant part:

> NDMA has been found to increase the occurrence of cancer in animal studies . . . Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.
>
> . . .
>
> The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.

161. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."

162. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

163. Anecdotally, NDMA has also been used in intentional poisonings.

***2. The Nitrosamine Contaminant NDEA***

164. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is soluble in water.

165. Like NDMA, NDEA is also classified by DHHS and EPA as a probable human carcinogen and a known animal carcinogen.

166. NDEA is an even more potent carcinogen than NDMA.

167. According to the EPA, even short-term exposure to NDEA can damage the liver in humans. Animal studies also demonstrate that chronic ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

168. Hematological effects were also reported in animal studies.

169. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high-to-extreme toxicity from oral exposure.

170. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."

171. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."

172. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.

173. The IARC of WHO classifies NDEA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

### *3. The Nitrosamine Contaminant NMBA*

174. Like NDMA and NDEA, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) is a yellow liquid.

175. NMBA has been labeled by the European Chemicals Bureau as "suspected of causing cancer."

176. NMBA has been referred to in an IARC publication as "carcinogenic *per se*."

177. After NMBA was detected in SCDs the FDA recognized that it is "a known animal and potential human carcinogen." The FDA's commissioner stated that the "the increased risk of cancer to patients with NMBA exposure appears to be the same for NDMA exposure."

### *4. Formation of NDMA, NDEA, and/or NMBA in Defendants' Adulterated, Misbranded, and/or Unapproved SCDs*

178. NDMA, NDEA, NMBA are considered genotoxic compounds, as they all contain

nitroso groups, which are gene-mutating groups.

179. The reason Defendants' manufacturing process produced these compounds is linked to the tetrazole group that most ARB drugs have, including SCDs. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA, NDEA, and NMBA, as a byproduct of the chemical reactions.

180. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.

### L. Defendants Had Actual and/or Constructive Notice of NDMA NDEA, and/or NMBA Contamination of Their Adulterated, Misbranded, and/or Unapproved SCDs

181. The FDA has concluded that "NDMA and NDEA are probable human carcinogens and should not be present in drug products." Likewise, the FDA's Commissioner stated that the presence of *any* NDMA, NDEA, or NMBA impurity "in drug products is not acceptable." As alleged above, the SCDs manufactured by the Defendants were found to contain dangerously high levels of nitrosamines, including NDMA and NDEA, sometimes reaching levels hundreds of times higher than the FDA's interim safety limits.

182. NDMA and NDEA are not FDA-approved ingredients for DIOVAN, EXFORGE, COZAAR, HYZAAR, AVAPRO, AVALIDE or their generic equivalents. Moreover, none of Defendants' SCDs identify NDMA, NDEA, NMBA, or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogen active ingredients and are not approved to be included in valsartan, losartan, or irbesartan API. Their inclusion in Defendants' SCDs renders the SCDs adulterated and misbranded compared to Defendants' warranties and representations.

183. If Defendants had not routinely disregarded the FDA's cGMPs, including those

discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately.

184. ZHP changed its valsartan manufacturing processes in or about 2012, if not earlier.

185. According to the European Medicines Agency ("EMA")—which has similar jurisdiction to that of the FDA—"NDMA was an unexpected impurity believed to have formed as a side product after [ZHP] introduced changes to its manufacturing process in 2012."

186. Most assuredly, NDMA and NDEA are not FDA-approved ingredients for DIOVAN, EXFORGE, COZAAR, HYZAAR, AVAPRO, AVALIDE or their generic equivalents. None of Defendants' SCDs identifies NDMA, NDEA, NMBA or any other nitrosamine as an ingredient on the products' labels or elsewhere. Their inclusion in Defendants' SCDs renders the SCDs adulterated and misbranded compared to Defendants' warranties and representations.

187. If Defendants had not routinely disregarded the FDA's cGMPs and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA, NDEA, and NMBA contamination almost immediately.

188. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

189. And as shown above, Defendants' own quality control units are and were

responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

190. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' SCDs would have been discovered in 2012 (or perhaps earlier for other API manufacturers). Defendants were thus on (at minimum) constructive notice that their SCDs were adulterated and/or misbranded as early as 2012.

191. However, there are indications that Defendants had actual knowledge of their SCDs' contamination with NDMA, NDEA, and NMBA and inadequate quality, and made efforts to conceal or destroy the evidence.

192. As alleged above, FDA investigators visited ZHP's facilities in May 2017. In the words of FDA inspectors, ZHP "invalidat[ed] [OOS] results [without] scientific justification" and did not implement "appropriate controls … to ensure the integrity of analytical testing," and routinely disregarded sampling anomalies suggestive of impurities.

193. These discoveries by the FDA's investigators suggest that Defendants were specifically aware of impurities in the drugs being manufactured by ZHP, including specifically contamination of Defendants' SCDs with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated and/or misbranded SCDs into the U.S. market.

194. Defendants were or should have been aware of ZHP's cGMP violations as early as 2012, if not earlier. Defendants were also, or should also have been aware of similar cGMP violations at Hetero and Aurobindo Defendants' API facilities.

195. And yet, Defendants knowingly, recklessly, and/or negligently introduced

adulterated and/or misbranded SCDs containing dangerous amounts of nitrosamines into the U.S. market. Defendants failed to recall their generic SCDs because they feared permanently ceding market share to competitors. And Defendants issued the "voluntary" recall of their SCDs only after the FDA had threatened an involuntary recall.

### M. FDA Announces Voluntary Recall of Defendants' Adulterated and/or Misbranded SCDs

196. On or about July 13, 2018, the FDA announced voluntary recalls by Defendants and other manufacturers for their SCDs manufactured by ZHP. The recall is for products distributed as early as October 2015. However, as alleged above, it is likely that Defendants' SCDs manufactured 2012 and beyond were also contaminated with NDMA and NDEA.

197. On or about July 27, 2018, the FDA announced expanded recalls of additional SCDs manufactured by Defendants and non-parties, and repackaged by third parties.

198. As stated in the FDA's July 13, 2018 statement:

> The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.

199. Subsequently, the FDA announced numerous additional recalls of SCDs and other similar products manufactured, distributed, or sold by Defendants as well as non-parties.

200. The recalls caused direct economic loss to Humana. When the FDA announced the recalls of SCDs, consumers were notified (by Humana and potentially by pharmacies or others) and were advised to obtain prescriptions for safe alternative drug to SCDs. Upon receipt of a prescription for a safe alternative drug, Humana insureds presented their prescriptions to be filled

at a pharmacy and they and Humana paid for replacement drugs. Upon receipt of substitute drugs, Humana insureds stopped using Defendants' inferior recalled SCDs, which were worthless and illegally sold to them. Humana thereby paid to replace the recalled SCDs with substitute drugs, effectively paying twice for drugs intended to treat the same medical conditions and for use over the same (or an overlapping) time period, when they should only have paid once.

## N. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic SCDs

201. Defendants made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated and/or misbranded SCDs.

### *1. General Warranties*

202. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book. The Orange Book is a public document; Defendants sought and received the inclusion of their SCD products in the Orange Book upon approval of their ANDAs. In securing FDA approval to market generic SCDs in the United States as an Orange Book-listed drug, Defendants were required to demonstrate that their generic SCDs was bioequivalent to their RLDs.

203. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMP.

204. Defendants' SCD(s) are accompanied by an FDA-approved label. By presenting consumers with an FDA-approved SCD label, Defendants, as generic manufacturers, made representations and express or implied warranties to consumers and TPPs of the "sameness" of their products to the SCD's RLD, and that their products were consistent with the safety, quality,

purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded or misbranded.

205. By introducing their respective SCDs into the United States market as a therapeutic equivalent to their RLDs and with the FDA-approved label that is the same as that of the RLDs, Defendants represent and warrant to end users and TPPs that their SCDs are in fact the same as and are therapeutically interchangeable with their RLDs. Much of the generic drugs supply chain, including the most critical components of that supply chain (end-user patients and reimbursing TPPs) rely on these representations and warranties.

206. In addition, Defendants affirmatively misrepresented and warranted to Humana through their websites, brochures, and other marketing or informational materials that their SCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

207. The presence of nitrosamines in Defendants' SCDs: (1) renders Defendants' SCDs non-bioequivalent (i.e., not the same) to their RLDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendants' SCDs non-therapeutically equivalent to their RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' SCDs containing an ingredient that is not also contained in their RLDs, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on Defendants' FDA-approved label). Defendants willfully, recklessly, or negligently failed to ensure their SCDs' labels and other advertising or marketing statements accurately conveyed information about their products.

208. The presence of nitrosamines in Defendants' SCDs and Defendants' serial and

willful failures to comply with cGMPs and other shortcomings in Defendants' generic drug manufacturing processes have resulted in Defendants' SCDs being adulterated and/or misbranded compared to Defendants' representations and warranties.

209. At all relevant times, Defendants have also impliedly warranted that their SCDs were merchantable and fit for their ordinary purposes.

210. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the EPA, NDMA and NDEA are not FDA-approved ingredients in SCDs. The presence of NDMA, NDEA, NMBA or other similar nitrosamines or impurities in Defendants' SCDs means that Defendants have violated implied warranties to Humana. The presence of NDMA, NDEA, or NMBA in Defendants' SCDs results in Defendants' SCDs being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

211. For these and other reasons, Defendants' SCDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants' to have introduced such SCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

212. Adulterated, misbranded, and/or unapproved SCDs contaminated with cancer-causing compounds are essentially worthless. No reasonable insurer (including Humana) would purchase (or reimburse for) these nitrosamine-laden SCDs. Nor could they, as an adulterated, misbranded, and/or unapproved SCD cannot even be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, and/or unapproved SCDs were worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved SCDs do not possess the same safety and efficacy profile as their branded equivalents. As such, the SCDs were not what they were supposed to be.

213. Moreover, every one of Humana's insureds who purchased and ingested a SCD has been exposed to a non-bargained for carcinogenic agent with mutagenic properties that operates at the cellular and sub-cellular levels, and may give rise to future potential health consequences.

214. The recalls were meant to quickly remove unsafe products from the market. While the FDA advised patients to continue taking SCDs, it only did so because of the risks associated with untreated high blood pressure.

215. In response to the recall, Humana contacted affected patients to advise them of the recall and to recommend that they contact their doctors to request a replacement or an alternative treatment option.

216. Because of the seriousness of the impurity—unsafe levels of a carcinogen— all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. SCDs had no use and were discarded.

***2. Teva Defendants' Specific Warranties***

217. Teva has a "Generics FAQs" on its website. In response to the question "Are generic drugs safe?" Teva states the following:

> A generic drug is bioequivalent to the original innovative drug and meets the same quality standards. The active ingredient, the content, the dosage form and the usage of a generic drug are similar to those of an innovative drug. Generic drugs are essentially the same as the original drug, but are offered at a lower price.

218. In response to the question "How do you ensure generic drug safety, having tried it in only a limited number of patients?" Teva states the following:

> The generic product's active pharmaceutical ingredient (API) is identical to that of the innovative drug, its purity profile is similar and it is found to be bioequivalent; therefore its safety and efficacy are also comparable.

219. Similarly, under the webpage titled "Uncompromising Quality," Teva states that

it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" with through Teva's "impeccable adherence to … [cGMPs][.]"

220. Teva's website states that "Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products."

221. According to Teva, "[o]ur manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals."

222. In a May 16, 2018 catalog of "all Teva and Actavis products," Teva, Actavis, Teva USA, Arrow, and Actavis Pharma all stated that their SCDs were "bioequivalent" to their RLDs.

223. Teva USA's website states, "Teva's commitment to quality is uncompromising and we manufacture according to the highest quality and compliance standards. This focus is evident at every stage of the development and production of our medicines. All of our manufacturing processes are validated and products are tested and certified, using state-of-the-art testing equipment throughout the manufacturing process designed to ensure adherence to the highest quality and compliance standards."

224. Teva USA's Code of Conduct affirms, "To ensure we are in compliance and working in accordance with sound quality principles in our research laboratories, in our clinical trials, and in our manufacturing plants and distribution centers, we adhere to the systems and

internal controls for 'Good Operating Practices,' or 'GxP,' including Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP)."

225. Teva USA maintains a Brand-to-Generic Medication Reference on its website. Before its recall of SCDs, this Reference included SCDs and their RLD equivalents.

***3. Hetero Defendants' Specific Warranties***

226. In touting itself, Hetero claims that it has "over 36 advanced manufacturing facilities strategically located across the world – including India, USA, China, Russia, Egypt, Mexico and Indonesia. Approved by stringent global regulatory authorities, Hetero facilities have integrated quality systems and processes to ensure adherence to cGMP (current Good Manufacturing practices). They are also vertically integrated and can be utilised for large-scale production of APIs, formulations in various dosage forms rapidly. We make continuous investments in upgradation of manufacturing facilities with special emphasis on deploying advanced machinery and adopting latest technologies to comply with 21 CFR. Besides enabling us consistently to produce high quality medicines at an affordable cost, it also helps us in passing through regulatory audits with relative ease. It is these advantages that make us the partner of choice for major global pharmaceutical companies."

227. Indeed, Hetero further describes itself as "a research-driven pharmaceutical company, is committed to the development, manufacturing and marketing of active pharmaceutical ingredients (APIs), intermediates and finished dosages. Today, Hetero is recognized as a world leader in process chemistry, API manufacturing, formulation development, manufacturing and commercialization. Hetero has around 18 state-of-the-art manufacturing facilities, which are cGMP compliant and have been approved by various Ministries of Health and regulatory authorities like US FDA, WHO, MCC - South Africa, MHRA-UK, TGA – Australia, PMDA –

Japan, KFDA (Korea) among others. The company has a rich manufacturing product portfolio of over 200 products across a wide range of therapeutic categories. Hetero has a strong global presence in over 120 countries and has been offering API's and generic formulations to partners across the globe. . . . . Hetero, a privately-owned company, is recognized as one of the top 10 companies in the Indian pharmaceutical industry with an annual turnover of US$ 1.2 billion. With a dedication and support of its 15,000 employees, Hetero continues its commitment to manufacture high-quality drugs and save millions of lives across the world."

228. Specifically with respect to its manufacturing of API, Hetero purports to be "proficient in achieving regulatory approvals worldwide of both APIs and formulations. With an integrated quality system to ensure adherence to cGMP practices, Hetero is committed to quality and its manufacturing facilities are approved by global regulatory agencies. In addition, Hetero continues to invest in its state-of-the-art manufacturing facilities and capabilities to ensure that it is able to provide the highest level of quality standards in the pharmaceutical industry."

229. Hetero likewise goes to great lengths in describing its products as the same as the brand name drugs. It states that its generic drugs are "copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs. . . . . Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the performance, safety or effectiveness of the generic drug. They

look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market. To find out if there is a generic equivalent for your brand-name drug, visit FDA.gov to view a catalog of FDA-approved drug products, as well as drug labeling. Since there is a lag time after generic products are approved and they appear in the "Orange Book", you should also consult the most recent monthly approvals for "First Generics" at FDA.gov."

230. Camber compares its valsartan to DIOVAN, its losartan to COZAAR, and its irbesartan to AVAPRO on its website's product catalog.

***4. Torrent Defendants' Specific Warranties***

231. Torrent Pharmaceutical's website states that they "strongly believe in providing quality medicines at affordable price to the patients. In this quest, primarily, we have inclined ourselves towards safeguarding both the qualitative and quantitative aspects with the help of our robust manufacturing technologies and manufacturing facilities."

***5. Aurobindo Defendants' Specific Warranties***

232. Aurobindo's website states that it is "Committed to Quality and Safety."

233. On January 6, 2015, Aurobindo announced that it had received FDA approval to manufacture and market valsartan, adding that valsartan is the "the generic equivalent to the reference listed drug product (RLD) Diovan®."

234. According to Aurobindo USA, "[a]s a truly integrated company, we assure continuity and quality from start to finish." Aurobindo also "[s]eek[s] to attain the highest quality standards."

235. Aurobindo USA's website lists DIOVAN as its valsartan's "Brand Reference," and likewise references COZAAR and HYZAAR as losartan "Brand Reference[s]."

236. Aurolife states: "The Aurolife family consists of an experienced management team with expertise in manufacturing, R&D, Quality Assurance and Quality control, finance and

regulatory affairs. Aurolife has 100,000 square feet state-of-the-art US FDA approved cGMP compliant manufacturing facility with an investment of over US $50 million."

**O. Fraudulent Concealment and Tolling**

237. Humana's causes of action accrued on the date the FDA announced the recalls of Defendants' generic SCDs.

238. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Humana their unlawful conduct. Defendants affirmatively strove to avoid disclosing their knowledge of their and ZHP's cGMP violations with respect to their SCDs, and of the fact that their SCDs were adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as their RLDs.

239. For instance, Defendants did not reveal to the public that their SCDs contained nitrosamines or were otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to their RLDs until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

240. To the contrary, Defendants continued to represent and warrant that their generic SCDs were the same as and therapeutically interchangeable with their RLDs.

241. Because of this, Humana did not discover, nor could Humana have discovered through reasonable and ordinary diligence, Defendants' deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Humana into believing that the prices paid for their SCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary

diligence.

242. As a result of Defendants' affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Humana has been tolled. Humana exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Humana was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

## FIRST CAUSE OF ACTION
## BREACH OF EXPRESS WARRANTIES

243. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

244. Humana formed contracts with Defendants at the time Humana purchased or reimbursed the SCDs. The terms of the contract include the promises and affirmations of fact made by Defendants on the SCDs' packaging and through marketing and advertising, including that the product would be bioequivalent to the name-brand medication, and would be of same "quality" and have the same safety and efficacy profile as the RLD. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Humana and Defendants.

245. Defendants expressly warranted that its SCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically equivalent to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

246. Defendants sold SCDs that they expressly warranted were compliant with cGMP and not adulterated or misbranded.

247. Defendants SCDs did not conform to Defendants' express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

248. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26- 1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2- 313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382- A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2- 313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

249. At the time that Defendants marketed and sold their SCDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the

same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Humana including but not limited to express representations made in referring to their SCDs as valsartan, valsartan HCT, amlodipine-valsartan, and and/or amlodipine-valsartan HCT.

250. Defendants breached their express warranties with respect to their SCDs as they were not of merchantable quality, were not fit for their ordinary purpose, and did not comply with cGMP and was adulterated and misbranded.

251. Humana would not have purchased or reimbursed the SCDs had Humana known these drugs were not the same as the RLD, did not contain the same ingredients, did not have the same safety and efficacy profile of the RLD, and contained NDMA and NDEA.

252. As a direct and proximate result of Defendants' breach of warranty, Humana has been injured and suffered damages in the amount of the purchase price of the medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the SCDs purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

## SECOND CAUSE OF ACTION
## BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS

253. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

254. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314;

Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84- 2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382- A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2- 314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

255. Defendants were merchants within the meaning of the above statutes.

256. Defendants' SCDs constituted "goods" or the equivalent within the meaning of the above statutes.

257. Defendants were obligated to provide Humana reasonably fit SCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

258. Defendants knew or should have known that their SCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly

warranted that their SCDs were of merchantable quality and fit for that purpose.

259. Defendants breached their implied warranty because Defendants' SCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

260. Humana purchased or reimbursed the SCDs in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

261. The SCDs were not altered by Humana or Humana's insureds.

262. As a direct and proximate result of Defendants' breach of implied warranty, Humana has been injured and suffered damages, in that Defendants' SCDs Humana purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

## THIRD CAUSE OF ACTION
## MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, ET SEQ.

263. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

264. Defendants are "warrantors" within the meaning of the Magnuson-Moss Warranty Act.

265. Humana and its members on whose behalf it reimburses drug costs are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

266. Defendants expressly or impliedly warranted their SCDs as alleged in the First and Second Causes of Action.

267. Under 15 U.S.C. § 2310(d)(1), Humana was "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal

and equitable relief." 15 U.S.C. § 2310(d)(1). Humana sues pursuant to this section to recover money damages and for legal and equitable relief.

268. Defendants have not acted on the opportunity to cure their failure with respected to their warranted SCDs.

269. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Humana is entitled to receive an award of attorneys' fees and expenses and pray for the same.

## FOURTH CAUSE OF ACTION
## FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)

270. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

271. Defendants affirmatively misrepresented material facts including, inter alia, that their SCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

272. Defendants omitted material facts including, inter alia, that their SCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

273. Defendants' actions had the effect of fraudulently inducing Humana to pay in whole or in part for Defendants' SCDs—products which Defendants knew or should have known were not therapeutically equivalent to their RLDs and/or did not comply with GMPs and/or were adulterated and/or misbranded. Humana would not have purchased Defendants' SCDs had Humana known the truth. Indeed, Humana could not have paid for Defendants' SCDs had Humana known the truth because Defendants' SCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Humana based on Defendants' fraudulent

misrepresentations and omissions.

274. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

275. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Humana to pay for some or all of the cost of Defendants' SCDs.

276. Defendants' misrepresentations and omissions were material.

277. Defendants' actively concealed their misrepresentations and omissions from Humana, government regulators, and the public.

278. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Humana to pay for Defendants' SCDs.

279. But for these misrepresentations and omissions, Humana would not have paid for Defendants' SCDs.

280. To the extent applicable, Humana was justified in relying on Defendants' misrepresentations and omissions. No reasonable insurer or pharmacy would have paid what they did for Defendants' SCDs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

281. Humana was damaged by reason of Defendants' misrepresentations and omissions alleged herein.

## FIFTH CAUSE OF ACTION
## NEGLIGENT MISREPRESENTATION AND OMISSION

282. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

283. Defendants had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of their SCDs.

284. Defendants failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of their SCDs.

285. Defendants negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of their SCDs.

286. Defendants' statements were false at the time the misrepresentations were made (or at the time omissions were not made).

287. Defendants knew, or reasonably should have known, that their representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Humana to purchase or reimburse Defendants' SCDs.

288. As a direct and proximate result of Defendants' acts and omissions described herein, Humana has suffered harm and will continue to do so.

289. Defendants' misrepresentations or omissions were material and a substantial factor in Humana's purchasing or reimbursing SCDs.

290. Defendants intended their misrepresentations or omissions to induce Humana to purchase or reimburse SCDs or had reckless disregard for same.

291. But for these misrepresentations (or omissions), Humana would not have purchased or reimbursed Defendants' SCDs.

292. Humana was justified in relying on Defendants' misrepresentations or omissions.

293. Humana was damaged by reason of Defendants' misrepresentations or omissions

alleged herein.

**SIXTH CAUSE OF ACTION**
**VIOLATION OF STATE CONSUMER PROTECTION LAWS**

294. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

295. Defendants have violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, et seq.;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, et seq.;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, et seq.;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, et seq.;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, et seq.;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, et seq.;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, et seq.;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq.;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, et seq.;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, et seq.;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, et seq.;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, et seq.;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, et seq.;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, et seq.;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, et seq.;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, et seq.; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq.;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, et seq.;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, et seq.;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, et seq.;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, et seq.;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, et seq.;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, et seq.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, et seq.;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, et seq.;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, et seq.;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, et seq.;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, et seq.;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, et seq.;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, et seq.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, et seq.;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, et seq.;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, et seq.;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, et seq.;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, et seq.; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, et seq.;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, et seq.;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, et seq.; and

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, et seq., the applicable statute for the Commonwealth of Puerto Rico.

296. Defendants' conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

297. Humana is engaged in consumer transactions affected by Defendants' misconduct within the meaning of the above statutes. Transactions involving Humana's members concern pharmaceuticals purchased primarily for personal, family, or household purposes.

298. To the extent applicable, Defendants knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants'

unfair methods of competition and unfair or deceptive acts or practices, Humana has suffered damages—an ascertainable loss—in an amount to be proved at trial.

**SEVENTH CAUSE OF ACTION**
**UNJUST ENRICHMENT**

299. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

300. As alleged herein, Defendants were unjustly enriched at the expense of Humana by virtue of the latter's paying for or reimbursing Defendants' SCDs.

301. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' SCDs were adulterated and misbranded, their distribution and sale in the United States was illegal.

302. Humana was unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' SCDs. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Humana as a result of their wrongful conduct alleged in this Complaint.

303. Humana is entitled to seek and does seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

**EIGHTH CAUSE OF ACTION**
**NEGLIGENCE**

304. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

305. Defendants owed a duty to Humana to use and exercise reasonable and due care in the manufacturing of its SCDs.

306. Defendants owed a duty to Humana to ensure that the SCDs they sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

307. Defendants owed a duty to care to Humana because they were the foreseeable, reasonable, and probable purchaser of SCDs and victim of Defendants' fraudulent and deceptive activities. Defendants knew, or should have known, that their SCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

308. Defendants failed to do this. Defendants inadequately oversaw the manufacture and sale of its SCDs. Defendants knew that ignoring the manufacturing issues surrounding their SCDs would damage Humana and increase its own profits.

309. Defendants maintained or should have maintained a special relationship with Humana, as they were obligated to ensure that their SCDs complied with cGMPs and were not adulterated or misbranded.

310. Defendants' own actions and inactions created a foreseeable risk of harm to Humana. Defendants' misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of their SCDs.

311. Defendants breached duties owed to Humana by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Humana.

312. As a direct and proximate result of Defendants' negligent conduct, Humana has suffered injury and is entitled to damages in an amount to be proven at trial.

## NINTH CAUSE OF ACTION
## NEGLIGENCE PER SE

313. Humana re-alleges and incorporates the preceding paragraphs as if set forth herein.

314. Defendants owed a duty to Humana to use and exercise reasonable and due care in the manufacturing of their SCDs.

315. Defendants owed a duty to Humana to ensure that the SCDs they sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

316. Defendants owed a duty to Humana because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards.

317. Defendants failed to comply with federal cGMPs and federal adulteration standards.

318. As a result of Defendants' failures to do so, Defendants' own actions and inactions created a foreseeable risk of harm to Humana.

319. As a direct and proximate result of Defendants' negligent conduct, Humana has suffered injury and is entitled to damages in an amount to be proven at trial.

## PRAYER FOR RELIEF

WHEREFORE, Humana prays for the following judgment:

A. A declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

B. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;

C. Payment to Humana of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the SCDs; the costs to replace or return SCDs because of recalls; Defendants' ill-gotten gains; and/or the increases in the amounts paid for non-adulterated, non-misbranded, SCDs in the wake of the recalls;

D. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies;

E. An award of statutory penalties to the extent available;

F. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

G. Such other and further relief as this Court may deem just, equitable, or proper.

**JURY DEMAND**

Plaintiff respectfully requests a trial by jury on all causes of action so triable.

Respectfully submitted,

/s/ *Benjamin E. Waldin*

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